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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/212,367	12/15/1998	DAVID BAUNOCH	98.714	8537

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 12/15/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/212,367

Applicant(s)

BAUNOCH ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-32 is/are allowed.
- 6) ☒ Claim(s) 2-5 and 33 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 Sept. 2003 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2-4 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al.(EP 0 508 568) in view of Kinney et al.(US 4,001,460).

With respect to claims 33, 3 and 4, the reference of Muller et al. discloses an apparatus which is capable of reprocessing a specimen from an infiltrating medium to an aqueous fluid which includes a processing chamber (112); means for regulating flow of fluid (120,129); pressure regulator for regulating pressure of the processing chamber (257,259,232); temperature regulator (117); containers (R1-R11) for holding a series of any known processing reagents; and a computer control system (276,286) which includes a processor and memory (See column 50, lines 11-25, which discloses a microcomputer).

While the specific examples of the system do not include the sequential reprocessing as recited in instant claim 33, the disclosure of Muller et al. discusses a known process that can be performed by the disclosed system. Paraffin treated tissue sections are heated then contacted with xylene (clearant agent), then contacted with ethanol (dehydrant agent) and then contacted with aqueous hydrogen peroxide and saline (aqueous fluid) (See page 8).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to control the disclosed system of the primary reference so as to perform the known reprocessing by sequential control of reservoirs containing the required reagents to reprocess the samples as

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suggested by the reference of Muller et al. Regulation of temperature, pressure and flow would have been obvious to one of ordinary skill in the art while providing the required contacting conditions between the tissue sample and reagent while maintaining the contacting efficiency of the system.

The claims further differ by reciting the presence of separately valved infiltrating fluid.

The reference of Kinney et al. discloses an automated processing system which is similar to that of Muller et al. In addition to the reagents suggested by the reference of Muller et al., the reference of Kinney et al. discloses the use of separately provided paraffin reservoirs (13, 14) (infiltrating fluid) which are separately controlled for flow with respect to the other treating agents and discloses the use of purge clearant (9) and purge dehydrant (10).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the modified primary reference of Muller et al. such that tissue samples may also be automatically processed as suggested by Kinney et al. for the known and expected result of increasing versatility of the system of Muller et al. since the system of Muller et al. is disclosed as an improved means for accomplishing the sequential, multi-step, controlled processing of a slide surface mounted material.

Note the controller of Muller et al. is capable of controlling the fluid flow selector (129) to connect any of the containers to the processing chamber in any sequence.

With respect to claim 2, the reference of Muller et al. also discloses the use of a rotary valve (129).

*Allowable Subject Matter*

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6. Claims 23-32 are allowed.

7. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claim 6, while the prior art of record discloses the use of purge dehydrant and/or purge clearant, the prior art of record fails to teach or fairly suggest a processor which controls the fluid flow selector so as to sequentially connect the processing chamber in a processing order which includes the container of clearing agent, the container of purge dehydrant, the container of dehydrant and then the container of aqueous solution to reprocess a specimen held in the chamber.

With respect to claims 23-32, while the prior art of record discloses the use of purge (contaminated) dehydrant and/or purge (contaminated) clearant, the prior art of record fails to teach or fairly suggest a processor which controls the fluid flow selector so as to sequentially connect the processing chamber in a processing order which includes the container of clearing agent, the container of contaminated dehydrant, the container of dehydrant and then the container of aqueous solution to reprocess a specimen held in the chamber.

***Response to Arguments***

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9. Applicant's arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

Applicants' comments state that the obviousness rejection of claims 1-2 has been mooted by canceling claim 1 from the application and amending claim 2 to be dependent upon claim 33. Applicants also argue that claims 3-4 should be independently patentable since they are no longer rejected under 35 USC 112, second paragraph.

In response, claims 3-4 were encompassed by the obviousness rejection applied to claims 1 and 2, these claims were inadvertently left out of the heading in the obviousness rejection section. Claims 3 and 4 are of the same scope as when they were addressed in the office action dated 17 April 2002 which is the same rejection as applied to claims 1 and 2 in the office action dated 26 March 2003. These claims have been included in the rejection of claim 33 over the combination of the references of Muller et al. and Kinney et al.

While claim 2 now depends from claim 33, claim 2 stands rejected because it depends from rejected claim 33 and the limitation of claim 2 is disclosed by the Muller et al. reference.

With respect to claim 33, while applicants' remarks state that new claim 33 should be allowable since it is claim 5 rewritten in independent format. However, new claim 33 does not include the specific limitation that deemed claim 5 allowable over the prior art of record.

Specifically, claim 5 included the claim limitations that the apparatus included "a container of purge dehydrant" and "the processor controlling the fluid flow selector in order to automatically and sequentially connect the processing chamber with the container of clearant agent, the container of purge dehydrant, the container of dehydrant agent and the container of aqueous solution in order to reprocess the specimen". While new claim 33 is limited to the same

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containers of reagents as encompassed by claim 5, claim 33 is devoid of the language "the processor controlling the fluid flow selector in order to automatically and sequentially connect the processing chamber with the container of clearant agent, the container of purge dehydrant, the container of dehydrant agent and the container of aqueous solution in order to reprocess the specimen" that was present in claim 5 and defined claim 5 over the prior art of record (See the reasons for the indication of allowable subject matter in section 10 of the office action dated 26 March 2003). The device encompassed by the combination of the references of Muller et al. and Kinney et al. discussed in the obviousness rejection above discloses all of the claimed structural elements recited in claim 33 and is structurally capable of reprocessing a tissue specimen.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006 (571-272-1269 after 12/16/03). The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920 (571-272-1281 after 12/16/03). The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
William H. Beisner  
Primary Examiner  
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WHB